

OFFICIAL
Expedited Examining Procedure
Group 3761

PATENT
Docket No. 54682US002 (formerly 54682USA6A)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Mary M. SWENSON) Group Art Unit: 3761 *9-4-0*
Serial No.: 09/507,108) Examiner: Kim M. Lewis
Confirmation No.: 7637)
Filed: 17 February 2000)
For: HIGH MOISTURE VAPOR TRANSMISSION RATE FOAM/FILM
COMPOSITE

RESPONSE UNDER 37 CFR §1.116

Assistant Commissioner for Patents
Attn: BOX AF
Washington D.C. 20231

Dear Sir:

The Final Office Action mailed 6 May 2002 has been received and reviewed. The pending claims are claims 1-35. Reconsideration and withdrawal of the rejections in view of the following comments are respectfully requested.

Telephone Interview

Applicant's Representative, Ann M. Mueting, thanks Supervisory Patent Examiner Glenn Dawson for the courtesy extended during a telephone interview held August 5, 2002. Also present was Kathleen L. Franklin, Reg. No. 47,574. The use of a declaration under 37 C.F.R. §1.132 to overcome novelty and obviousness rejections, and U.S. Pat No. 5,409,472, Rawlings et al. were discussed.

Amendment and Response - Appendix A

Page 2A of 5A

Applicant(s): Mary M. SWENSON

Serial No.: 09/507,108

Filed: 17 February 2000

For: HIGH MOISTURE VAPOR TRANSMISSION RATE FOAM/FILEM COMPOSITE

The Declaration Under 37 CFR 1.132 filed 3/26/02

The Examiner stated in the Office Action at page 2, paragraph 3, that the declaration filed in the present application on March 26, 2002, is insufficient to overcome the rejection of claims 1-9, 11-16, 18, 19, 22-27, 29-32, 34 and 35 under 35 U.S.C. §102(b) because "declarations filed under 1.132 can not be used to overcome a rejection under 35 U.S.C. 102." Applicant is unaware of such a *per se* rule and respectfully requests the Examiner indicate where this rule may be found.

It is Applicant's understanding, according to the Manual of Patent Examining Procedure (MPEP) that "[E]vidence traversing rejections must be considered by the examiner whenever present." MPEP 716.01. Additionally, caselaw indicates that extrinsic evidence may be used in an anticipation analysis when a document is silent regarding a characteristic asserted to be intrinsic. "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Furthermore, during the telephone interview between Applicant's Representative and Supervisory Patent Examiner Dawson, hereinabove referenced, Examiner Dawson did not affirm the existence of a *per se* rule preventing the use of declarations under 37 C.F.R. §1.132 in overcoming an anticipation rejection.

It is not clear to Applicant how to overcome an anticipation rejection in the instance when the cited document is silent regarding features of the disclosed invention without being able to rely on extrinsic evidence, such as the declaration filed in the present application. Furthermore, it is Applicant's belief, based on the above comments, that the Examiner is required to consider the evidence submitted in the filed declaration. Therefore, Applicant respectfully requests the Examiner consider the evidence presented in the Declaration of Mary M. Swenson, filed March 26, 2002.

The Examiner also stated in the Office Action at page 2, paragraph 4, that the declaration filed March 26, 2002, is insufficient to overcome the 103 rejection of claims 10, 17,

Amendment and Response - Appendix A

Page 3A of 5A

Applicant(s): Mary M. SWENSON

Serial No.: 09/507,108

Filed: 17 February 2000

For: HIGH MOISTURE VAPOR TRANSMISSION RATE FOAM/FILM COMPOSITE

20, 21, 28, and 33 because there is no nexus between the subject matter of the declaration and the subject matter of the claims. It is unclear to Applicant whether the evidence contained in the declaration was considered or not with respect to the 103 rejection of claims 10, 17, 20, 21, 28, and 33. If the declaration was not considered, Applicant respectfully asserts that the Examiner must consider the evidence. "Evidence traversing rejections must be considered by the examiner whenever present." (MPEP 716.01) and "[O]ffice personnel should consider all rebuttal arguments and evidence presented by Applicants." (MPEP 2144.08(I)(B)). If the declaration was not considered, Applicant respectfully requests that the rejection be withdrawn and that the Examiner consider the evidence presented in the declaration.

If, however, the evidence contained in the declaration was considered and found insufficient, Applicant respectfully disagrees and requests that the Examiner specifically explain why there is "no nexus" between the subject matter of the declaration and the subject matter of the claims 10, 17, 20, 21, 28, and 33 rejected under 103, as required under MPEP 716.01(B).

The use of the phrase "no nexus" is unclear. If the Examiner intended to use the phrase "no nexus" merely to indicate that there is no connection between the subject matter of the declaration and the subject matter of the claims rejected under 103, Applicant disagrees. Claims 10, 17, 20, 21, 28, and 33 all depend from independent claims reciting a substantially nonswellable foam. In comparison, the declaration indicates that samples of selected foams used in the dressings of Rawlings et al. have swell values of at least 60%. Applicant respectfully submits there is a substantial connection between the evidence included in the declaration and Applicant's claims and, therefore, the declaration should be accorded substantial weight. Therefore, Applicant respectfully submits that the Examiner must consider the evidence presented in the declaration filed in the present application.

For the foregoing reasons, Applicant submits that the Examiner is required to consider the evidence as presented in the Declaration of Mary M. Swenson, filed March 26, 2002, and requests the finality of the present Office Action be withdrawn to consider the evidence presented in the declaration.

Amendment and Response - Appendix A

Page 4A of 5A

Applicant(s): Mary M. SWENSON

Serial No.: 09/507,108

Filed: 17 February 2000

For: HIGH MOISTURE VAPOR TRANSMISSION RATE FOAM/FILM COMPOSITE**The 35 U.S.C. §102 Rejection**

The Examiner rejected claims 1-9, 11-16, 18, 19, 22-27, 29-32, 34, and 35 under 35 U.S.C. §102(b) as being anticipated by Rawlings et al. (U.S. Patent No. 5,409,472). Applicant respectfully traverses this rejection.

Applicant has specifically selected a substantially nonswellable foam as a component of the claimed medical articles. Rawlings et al., on the other hand, do not necessarily teach a substantially nonswellable foam. That is, while one or more of the foams disclosed in Rawlings et al. may be substantially nonswellable, Rawlings et al. neither specifically disclose the swellability properties of the foams, nor do they provide either guidance or motivation to one of skill in the art to specifically select those foams which are substantially nonswellable.

The Examiner contended that because the chemistries of the foams of Rawlings et al. have some overlap with the chemistries of Applicant's foams, it would follow that both foams necessarily have the same properties. In other words, it appears to be the Examiner's position is that because Applicant's foams are substantially nonswellable, the foams of Rawlings et al. are inherently also substantially nonswellable. Applicant respectfully disagrees.

"The doctrine of inherency is available only when the prior inherent event can be established as a certainty. That an event may result from a given set of circumstances is not sufficient to establish anticipation." *Ethyl Molded Products Co. v. Betts Package Inc.*, 9 USPQ2d 1001, 1032 (DC Eky 1988). (See also, *In re Oelrich and Divigard*, 666 F.2d, 212 USPQ 323 (CCPA 1981). "Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (quoting *Hansgirg v. Kemmer*, 40 USPQ 665, 667 (CCPA 1939)). Applicant's substantially nonswellable foams may include polyurethanes (Specification, page 6, line 26). Additionally, Rawlings et al. disclose the use of certain polyurethane foams prepared from HYPOL FHP 2000, 2001, 3000, 3001, 2002 and 2000HD isocyanate terminated polyethers (Rawlings et al., column 7, lines 18-20). However, as evidenced by the Declaration of Mary M. Swenson, filed March 23, 2002,

Amendment and Response - Appendix A

Page 5A of 5A

Applicant(s): Mary M. SWENSON

Serial No.: 09/507,108

Filed: 17 February 2000

For: HIGH MOISTURE VAPOR TRANSMISSION RATE FOAM/FILM COMPOSITE

samples of foams prepared from HYPOL 2000 and HYPOL 2002 and obtained from Dow had swell values of at least 60%. Applicant, therefore, submits that although there is some overlap in chemistries between Applicant's substantially nonswellable foams and the foams of Rawlings et al., the evidence of swellability of HYPOL 2000 and 2002, foams included in Rawlings et al., fails to establish as a certainty that the Rawlings et al. foams are necessarily inherently substantially nonswellable.

Furthermore, for inherency to apply, the missing descriptive information must necessarily be present in the cited document such that one of skill in the art would recognize such a disclosure. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill'" *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949, 1950-1951 (Fed. Cir 1999) (quoting *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991)). Applicant submits that although Rawlings et al. disclose that distortion of the dressing as a result of potential dimensional changes in the absorbent layer (e.g., by expansion in liquid uptake) is not desirable, they fail to make clear that the foams themselves are necessarily substantially nonswellable. Additionally, as Rawlings et al. fail to provide guidance as to swellability of disclosed foams, there is no reasonable likelihood that one of skill in the art could have discovered or recognized which, if any, of the disclosed foams of Rawlings et al. are substantially nonswellable.

Additionally, Applicant herewith submits European Patent Specification 0 171 268 B1 (Exhibit A) as further indication that the foams of Rawlings et al. are not necessarily substantially nonswellable. EP 0 171 268 B1 discloses an absorbent wound dressing suitable for use in deep cavernous and exuding wounds (EP 0 171 268 B1, column 1, lines 5-6). The dressing includes pieces of a hydrophilic foam in a porous bag that swells on absorption of wound exudates, conforming to the contours of the wound (EP 0 171 268 B1, column 2, lines 20-29). "It is desirable that the foam will swell on absorbing exudate", allowing the dressing to adjust to changing wound contours (EP 0 171 268 B1, column 3, lines 4-6). Preferred foams

Amendment and Response - Appendix A

Page 6A of 5A

Applicant(s): Mary M. SWENSON

Serial No.: 09/507,108

Filed: 17 February 2000

For: HIGH MOISTURE VAPOR TRANSMISSION RATE FOAM/FILM COMPOSITE

include those made from HYPOL FHP 2000, 2001, 3000, 3001, 2002 and 2002HD isocyanate terminated polyethers (EP 0 171 268 B1, column 4, lines 62-64). These are the same materials used to prepare the foams disclosed in Rawlings et al. (Rawlings et al., column 7, lines 18-20). As EP 0 171 268 B1 indicates their foams desirably will swell (i.e., are not substantially nonswellable), and further specifically names suitable foams are those made from HYPOL FHP 2000, 2001, 3000, 3001, 2002 and 2002HD isocyanate terminated polyethers, Applicant submits that the foams of Rawlings et al., which may also incorporate foams prepared from these HYPOL isocyanate terminated polyethers, are also not necessarily substantially nonswellable.

Finally, Applicant submits herewith Exhibit B, a product brochure from the Dow Chemical Company including information regarding foams and gels made from HYPOL prepolymers. At page 3 of the brochure, below Table 1, it is discussed that the foams and gels obtained from the HYPOL prepolymers exhibit high levels of hydrophilicity, the foams typically absorbing 20 to 30 times their own weight in water. The foams and gels will release water through evaporation, shrinking in the process. Applicant submits that this disclosure indicates that foams prepared from these HYPOL prepolymers substantially provide and determine the swellability of a product that incorporates them.

Applicant further submits that it is neither taught nor suggested that any additional components may be added to substantially change the swellability of such product. That is, there is no teaching or suggestion in the cited documents that anything can be added to the foams prepared from the HYPOL prepolymers to make them substantially nonswellable.

Applicant submits that as the present claims recite medical articles that include a substantially nonswellable foam, and that Rawlings et al. neither teaches nor suggests foams that are necessarily substantially nonswellable, nor provides specific guidance to one of skill in the art to select a substantially nonswellable foam, the present claims are novel over Rawlings et al. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

Amendment and Response - Appendix A

Page 7A of 5A

Applicant(s): Mary M. SWENSON

Serial No.: 09/507,108

Filed: 17 February 2000

For: HIGH MOISTURE VAPOR TRANSMISSION RATE FOAM/FILM COMPOSITE**The 35 U.S.C. §103 Rejection**

The Examiner rejected claims 10, 17, 20, 21, 28, and 33 under 35 U.S.C. §103(a) as being unpatentable over Rawlings et al. (U.S. Patent No. 5,409,472) in view of Ward (U.S. Patent No. 5,000,172). Applicant respectfully traverses this rejection.

As indicated above, Rawlings et al. do not teach or suggest foams that are necessarily substantially nonswellable. Furthermore, Ward also does not teach or suggest substantially nonswellable foams in a medical article. Therefore, Ward does not provide that which is missing from Rawlings et al.

As Rawlings et al. do not teach foams that are necessarily substantially nonswellable, and do not suggest the selection of substantially nonswellable foams, and Ward neither teaches nor suggests substantially nonswellable foams, Applicant respectfully submits that the present claims are nonobvious over Rawlings et al. and Ward. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

Summary

It is respectfully submitted that the pending claims 1-35 are in condition for allowance and notification to that effect is respectfully requested.

Amendment and Response - Appendix A

Page 8A of 5A

Applicant(s): Mary M. SWENSON

Serial No.: 09/507,108

Filed: 17 February 2000

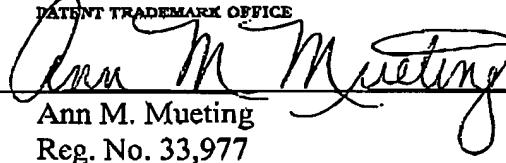
For: **HIGH MOISTURE VAPOR TRANSMISSION RATE FOAM/FILM COMPOSITE**

The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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PATENT TRADEMARK OFFICE

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Date
August 30, 2002**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on this 30th day of August, 2002, at 11:53 a.m. (Central Time).

By: Rachel England-CarsonName: Rachel England-Carson